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STATE OF COLORADO

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Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

October 5, 1999

Ms. Bonita Lavelle
EPA Region 8
999 18th Street, Suite 500
Denver, CO 80202-2466

Re: Draft Quality Assurance Project Plan (QAPP) for Vasquez Boulevard/I-70 Bioavailability of Arsenic in Site Soils Using Juvenile Swine as an Animal Model (September 1999).

Dear Ms. Lavelle:

The Colorado Department of Public Health and Environment (CDPHE) has received and reviewed the above-referenced document. As stated in our September 17, 1999 letter to you, CDPHE does not endorse the implementation of this study without thorough evaluation and comment by our staff and other members of the VBI-70 Working Group. Consequently, we may not be able to support the results of this study for use in the Baseline Risk Assessment. You will find our comments attached.

The state submitted a preliminary comment via email (9/7/99) requesting clarification of EPA's decision to eliminate PAX as a test material from the study. In verbal comments to the state (6/9/99), EPA had considered using a portion of the PAX sample for this purpose. It may be helpful to understand EPA's rationale for considering it initially and then deciding against it.

Please do not hesitate to contact me at (303) 692-3395 if you have any comments or questions.

Sincerely,

Barbara O'Grady

Barbara O'Grady
State Project Manager

cc: VB/I-70 Working Group
File VAS 4.1.0

State of Colorado Comments
on the Draft Quality Assurance Plan for Vasquez Boulevard/I-70
Bioavailability of Arsenic in Site Soils Using Juvenile Swine as an Animal Model
(September 1999)

General Comments

1. For clarity, it would be helpful to add a description in the project plan of the proposed phases of the swine study. SOP #4 refers to growth curves determined in a Phase I study, but this phased approach is never described in the study protocol. Also, the statement on page 16 in section D1 ("...Qualitative professional judgement will be used to interpret the results of the chemical and biological data collected which is intended to be screening-level preliminary data..") is confusing. Does this imply this project plan is describing a pilot study or initial phase of testing only?

2. The study design calls for dosing test animals with three test materials and states (on page 11) that "...a memo documenting specific test materials will be prepared prior to commencement of each study". It is important that all interested parties have an understanding of how these test materials will be selected. Because not much appears to be known about how certain physical or chemical parameters such as grain size or mineralogy may affect the kinetics of arsenic bioavailability, selection of representative test materials will be key to the utility and applicability of the study to site conditions.

3. Evaluation of the utility of the swine model as a "plausible surrogate for arsenic absorption in humans" would be greatly improved by analyzing for various arsenic metabolites (As+3, As+5, DMA and MMA) present in urine, rather than analyzing only for total arsenic. Although the GI system of swine may be similar to humans, not much is known about how metabolism of arsenic compares in humans versus swine. Large differences in methylation capacity of different animal species have been widely recognized, which raises a concern for potential misinterpretation of study results based on total arsenic data only. While speciation would add somewhat to the analytical costs of the study, we believe it would greatly assist with the interpretation of the results and lessen the uncertainty of applying these bioavailability estimates to the VB-I70 neighborhood.

Specific Comments

1. Page 7 - Unless convincing information already exists about the dose-dependence of arsenic absorption in swine, DQO Stage 1 should include, as a primary or secondary

question, determination of whether arsenic absorption is concentration-dependent. This may be particularly important to the study of arsenic absorption because of potential differences in methylation capacity at high dose levels. Because the current study design utilizes analytical measures based only on total arsenic, it would not be possible to distinguish between significant differences in excretion of inorganic As (relatively toxic form) and other less toxic methylated forms of arsenic (such as DMA or MMA).

2. Page 11 - Ideally, the dosing range selected should include a lower dose, more typical of an actual, anticipated environmental exposure. Also, as discussed above in the previous comment, the dosing range selected should be adequate to determine if absorption is dose dependent.

3. SOP #2 - Check standards should be comparable to the range of concentrations being used in this study. The standards proposed represent only the lower end of the dosing range.

4. SOP #9 - The list of biological samples which will be collected needs to be updated for this study. The SOP currently states that blood, tissue and bone will be collected, rather than urine and fecal matter.

5. The project plan needs to include an SOP for collecting and analyzing fecal material.